Feasibility, Safety, and Efficacy of MicroNet-covered stent in consecutive increased-risk iliac stenotic lesions to reconstruct anatomy and guard effective flow: A multi-center, multi-specialty study

FLOWGUARD-ILIAC, NCT04461717

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Disclosure

Speaker name:

Piotr Paluszek

I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☑ I do not have any potential conflict of interest

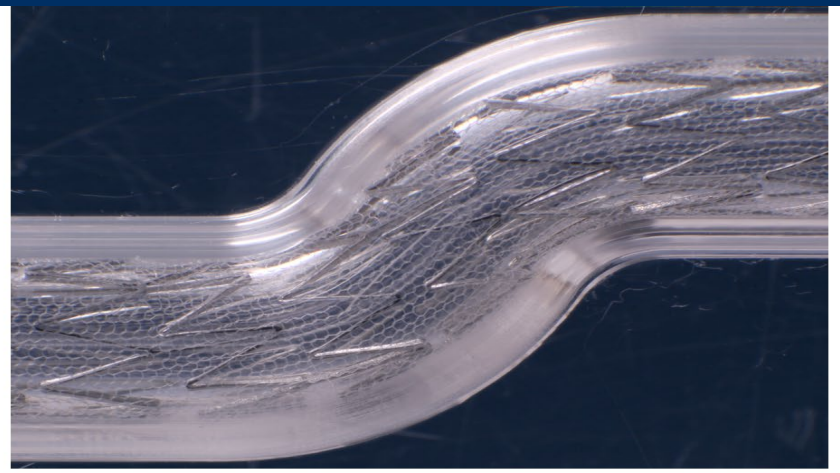
Background

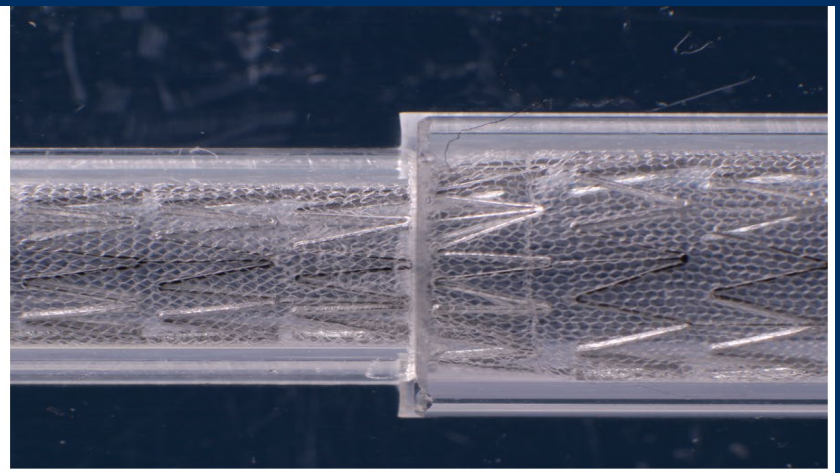
In **increased-risk lesions,** conventional (single-layer) stents used in iliac artery revascularization have important limitations:

- **highly-calcific stenoses** (risk of perforation limits stent optimization whereas suboptimal expansion is a risk factor for in-stent restenosis)

- **thrombotic lesions** (where the “cheese-grater” effect may lead to distal embolism)

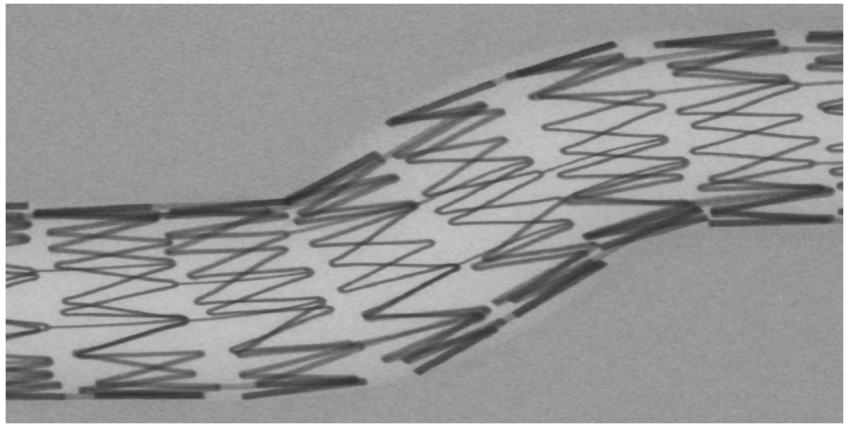
Unique combination of Radial force, High conformability, + MicroNET coverage: Enabling Endovascular Reconstruction

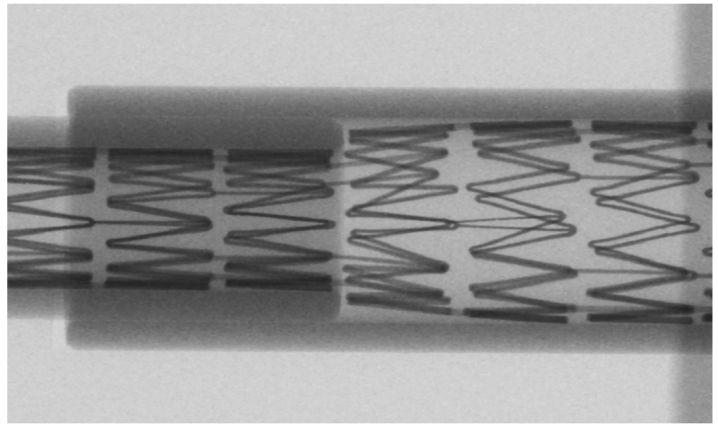




Stent adaption in a curved and in a straight vessel model with an inner diameter step from 7 to 5 mm for InspireMD CGUARD

(**macrophotography**)





Stent adaption in a curved and in a straight vessel model with an inner diameter step from 7 to 5 mm for InspireMD CGUARD

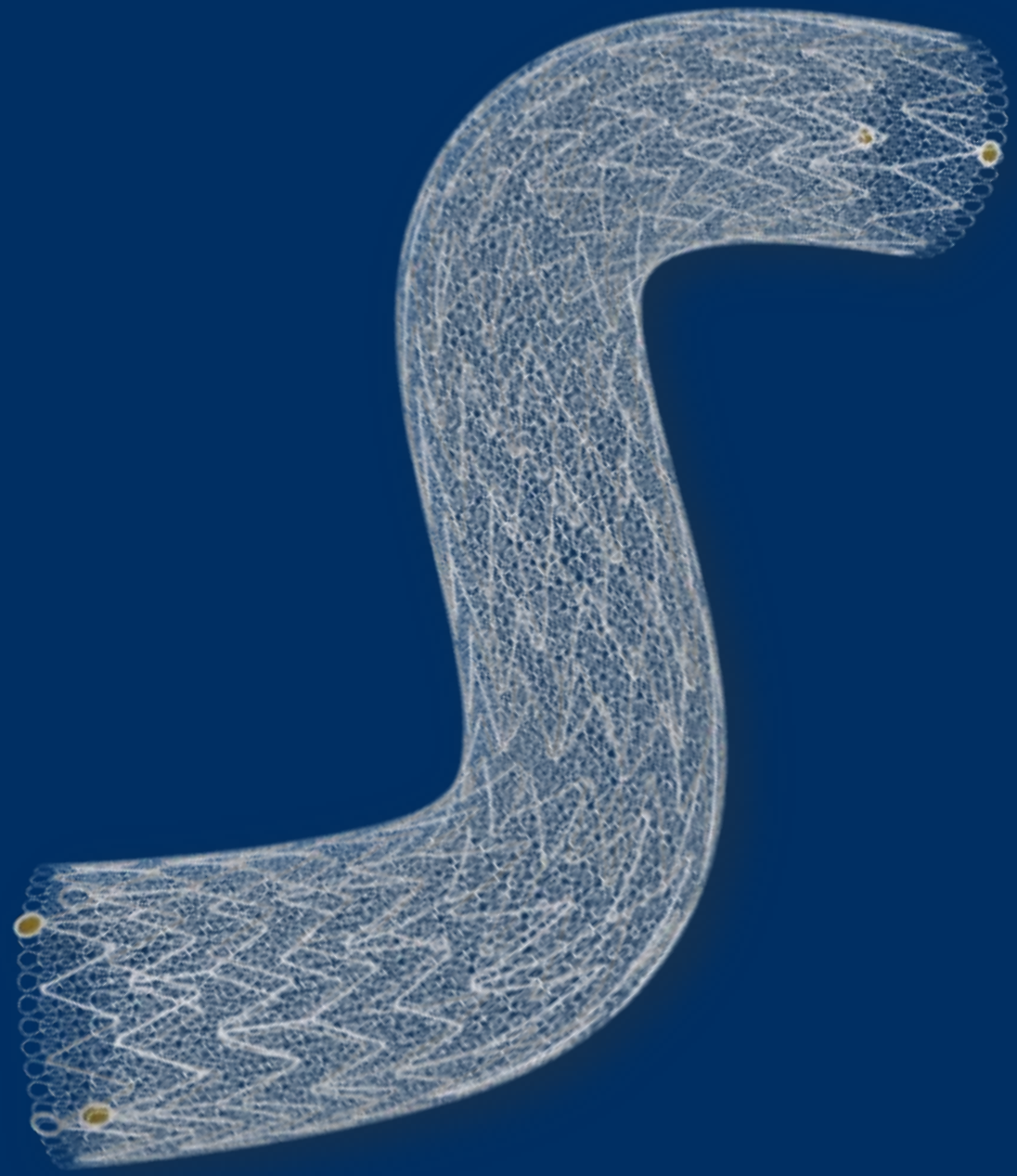
(**micro CT**)

C Wissgott JEVT 2017, VEITH 2018

P Musialek @ ICI 2018

MicroNET-covered stent

- has the ability to sequestrate the atherothrombotic material
- in highly calcific lesions, due to a degree of sealing properties, enables high-balloon diameter, high-pressure optimization of the angiographic result and may minimize residual stenosis
- hence its potential to improve the outcomes



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Aim of the FLOWGUARD-ILIAC study NCT04461717

Investigator-initiated, industry-independent study to test, in a multi-center, multi-specialty (vascular surgery, radiology, angiology, cardiology) setting, the use of **MicroNET-covered stent** to treat **increased-risk iliac lesions, in consecutive patients** undergoing percutaneous iliac artery revascularization (claudicants or iliac-related limb-threatening ischaemia).

Methods:

1. ”Increased-risk lesion” by CT angio/ catheter angiography

   Consensus by the operator intending to perform the case

   + 2 other operators

2. Internal iliac artery coverage to be avoided.

3. Active recruitment: 24 months (COVID-19 break).

FLOWGUARD-ILIAC Investigators

Patients

n = 65

41 Men (63.1%)

24 Women (36.9%)

Age: 53-83, mean age 68.6 years

Claudicants – 59 (90.8%)

Critical limb ischemia – 6 (9.2%)

Coronary artery disease	41 (63.1 %)
Congestive Heart Failure	14 (21.5%)
Previous stroke	14 (21.5%)
Hypertension	63 (97%)
Dyslipidaemia	65 (100%)
Diabetes/glucose intolerance	33 (50.8%)
Carotid Artery Disease	32 (49.2%)
Previous PCI/CABG	25 (38.5%)
Previous CAS/CEA	22 (33.8%)
Smoking	Current – 21 (32.3%) Past – 37 (57%) None – 7 (10.7%)

The iliacs treated

Side:

- Left – 20 patients
- Right – 38 patients
- Both – 7 patients

Artery:

- LCIA – 20 (26.0%)
- RCIA – 24 (31.2%)
- LEIA – 10 (13.0%)
- REIA – 23 (29.8%)

Lesion characteristics n=77

- Highly–calcific **34 (44.1%)**
- Thrombotic (incl. thrombotic dissection) **35 (45.5%)**
- Other high–risk **8 (10.4%)**

Mean stenosis severity before the procedure **82.7 ± 9.3% (angiolab analysis)**

Complex CTO recanalization – 4 arteries (5.2 %)

Stents used

65 patients

77 arteries

80 stents

Nominal diameter
7 – 10 mm
mean 9.4 mm

Length
20 – 60 mm
mean 36.3 mm

DIAMETER	7 mm	11
	8mm	14
	9 mm	21
	10mm	34
LENGTHS	20mm	9
	30mm	25
	40mm	36
	60mm	10

No stents other than the study device were used.

Procedure

Access	
Femoral	50
Femoral bilateral	5
Radial	8
Brachial	2

Predilatation

34 arteries (44.1%)

Balloon diameters

3.5 – 8 mm

average 5.3 mm

Pressures

6 – 24 atm

average 14.8 atm

Postdilatation

77 arteries (100%)

Balloon diameters

6 – 10 mm

average 7.6 mm

Pressures

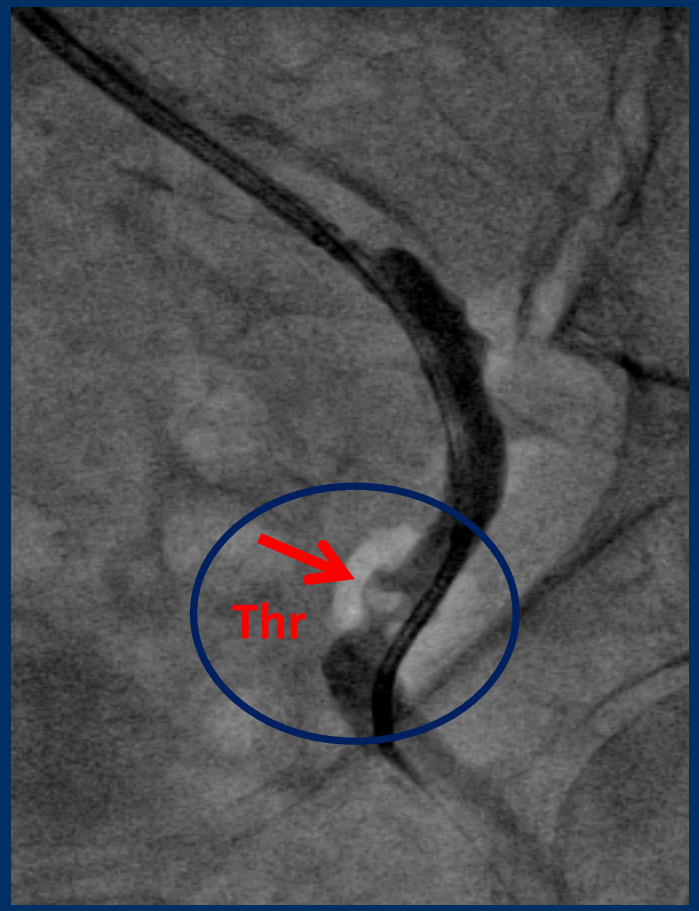
8 – 24 atm

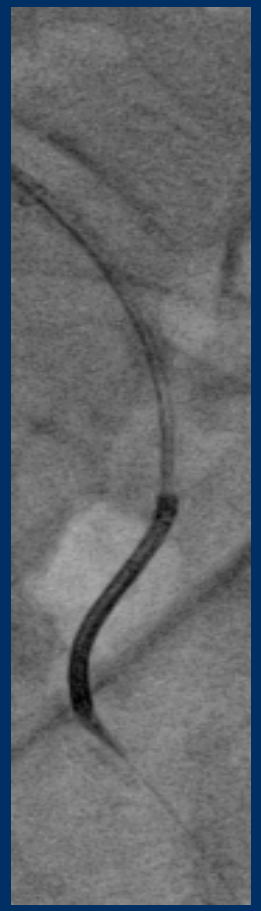
average 15.4 atm

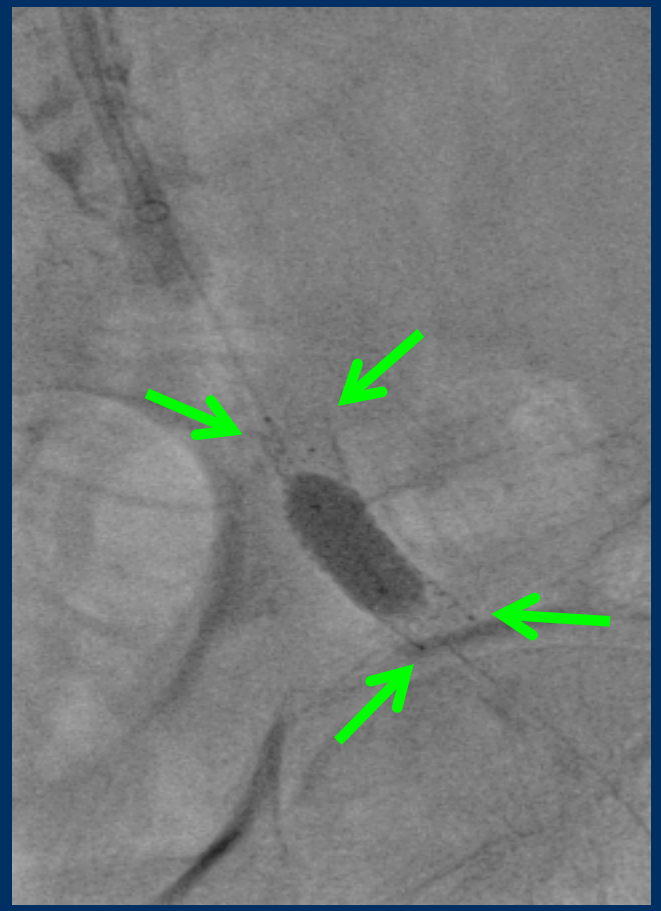
Immediate results

- Procedure performed with intended device - 100%
- Technical success (residual stenosis below 30%) – 100%
- Clinical success (technical success + no MACE) – 100%
- Residual stenosis: **8.0 ± 6.3 %**
- Complications:
  - Death/MI/Stroke/Transfusion-requiring bleeding: 0
  - Perforation: 0
  - Embolism: 0
  - Groin hematoma: 2 (3.1%)

Thrombus-containing/high-embolic risk lesions in iliacs







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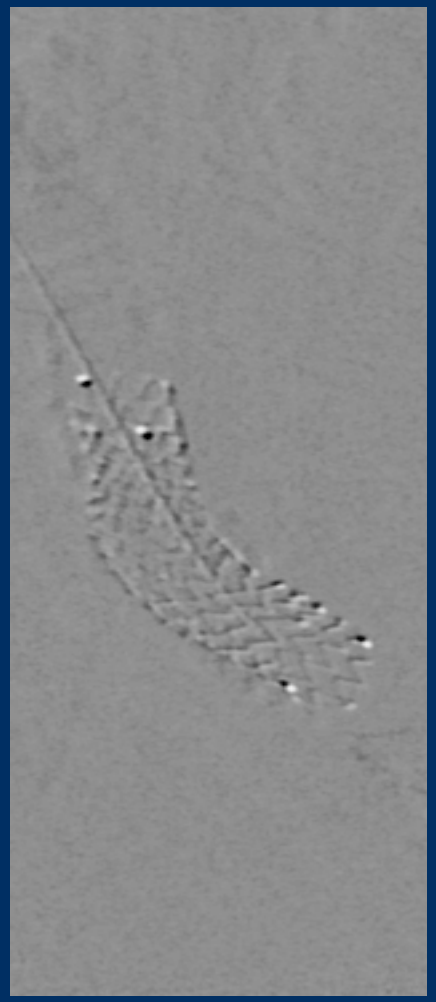
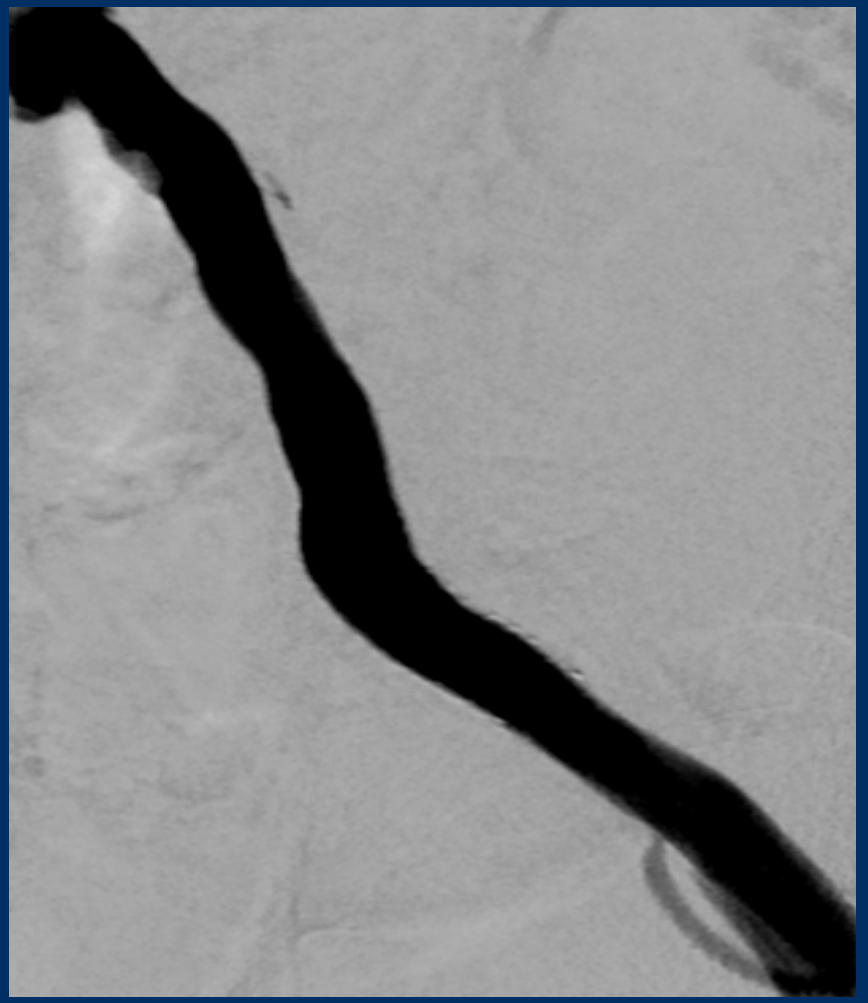
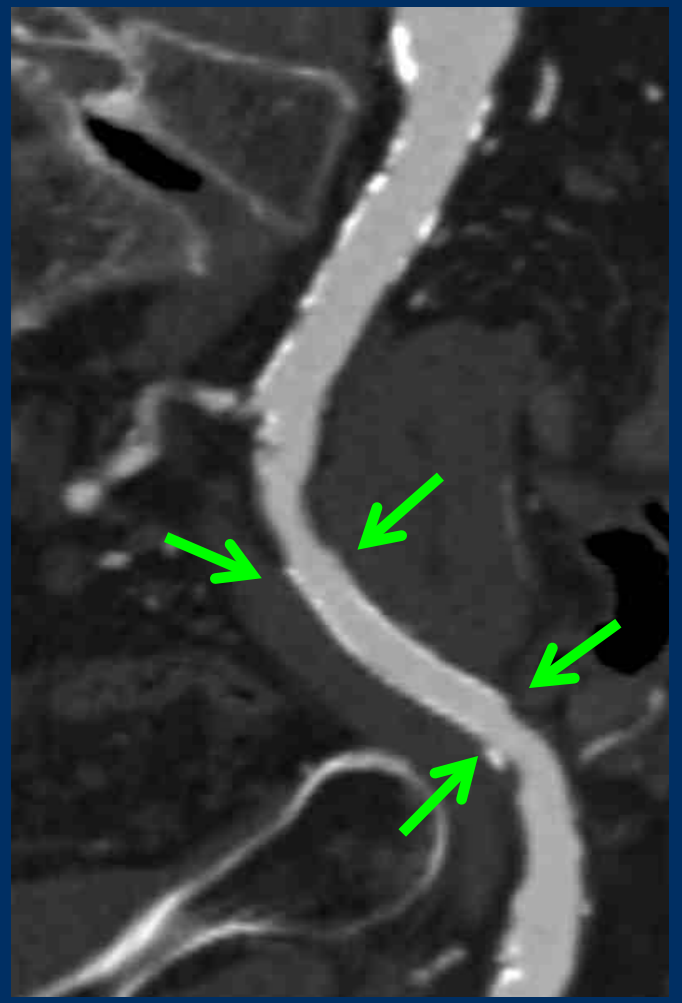
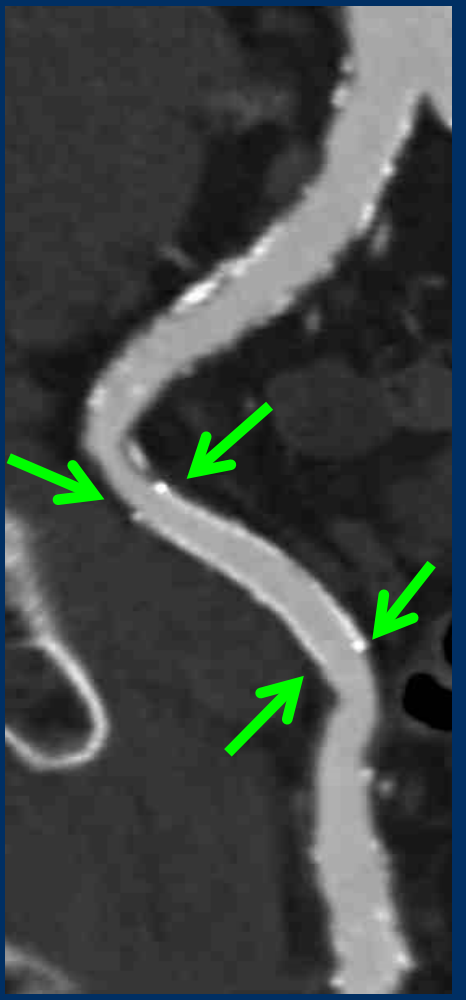




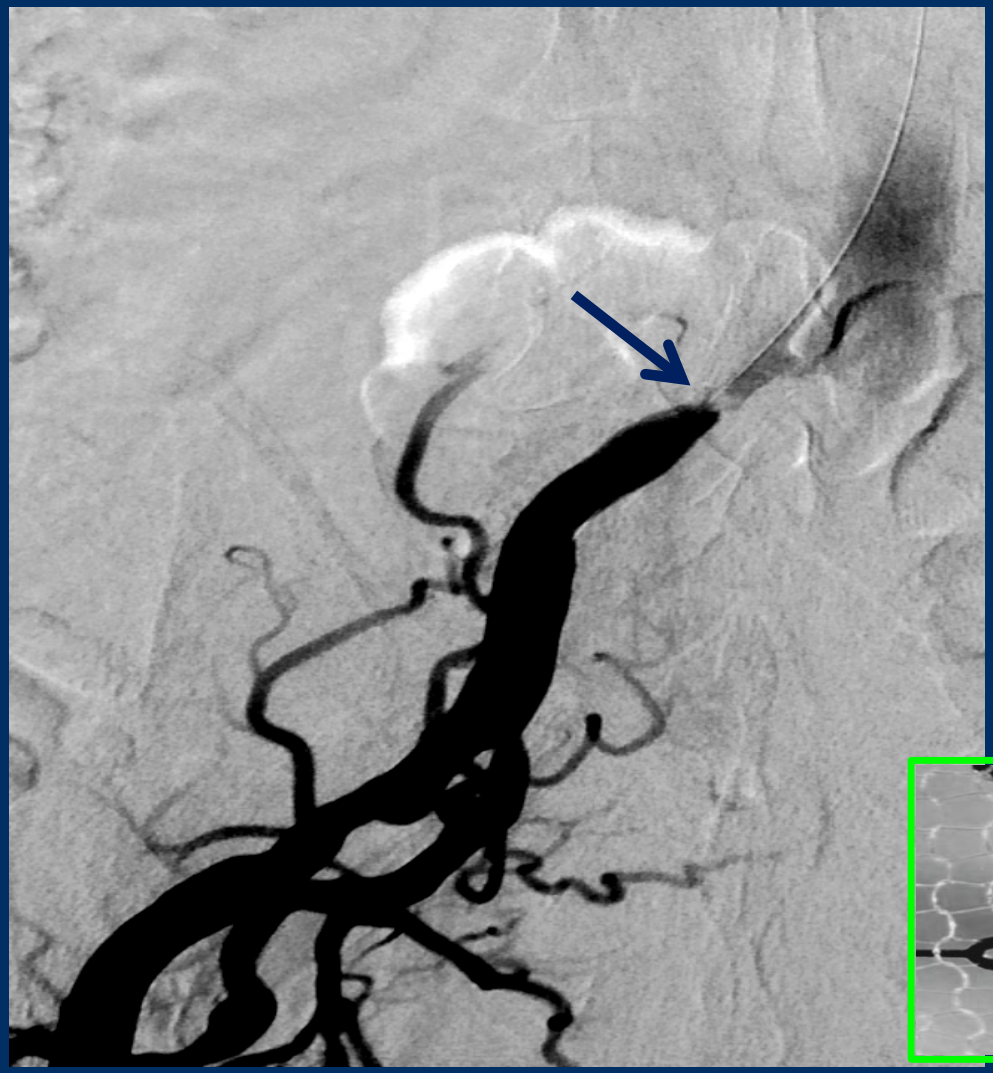
Optimal procedural result

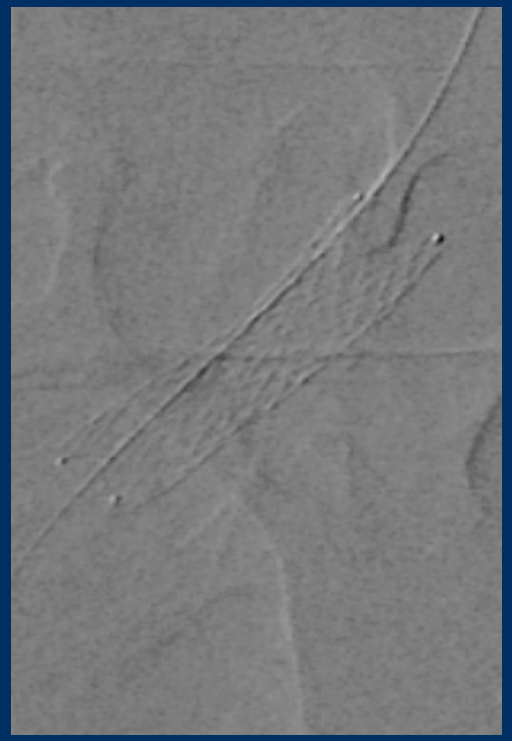


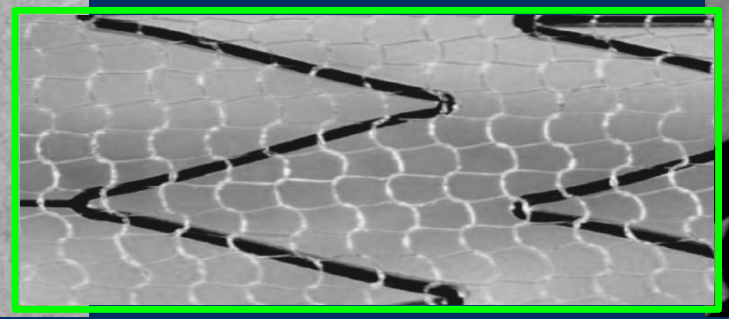


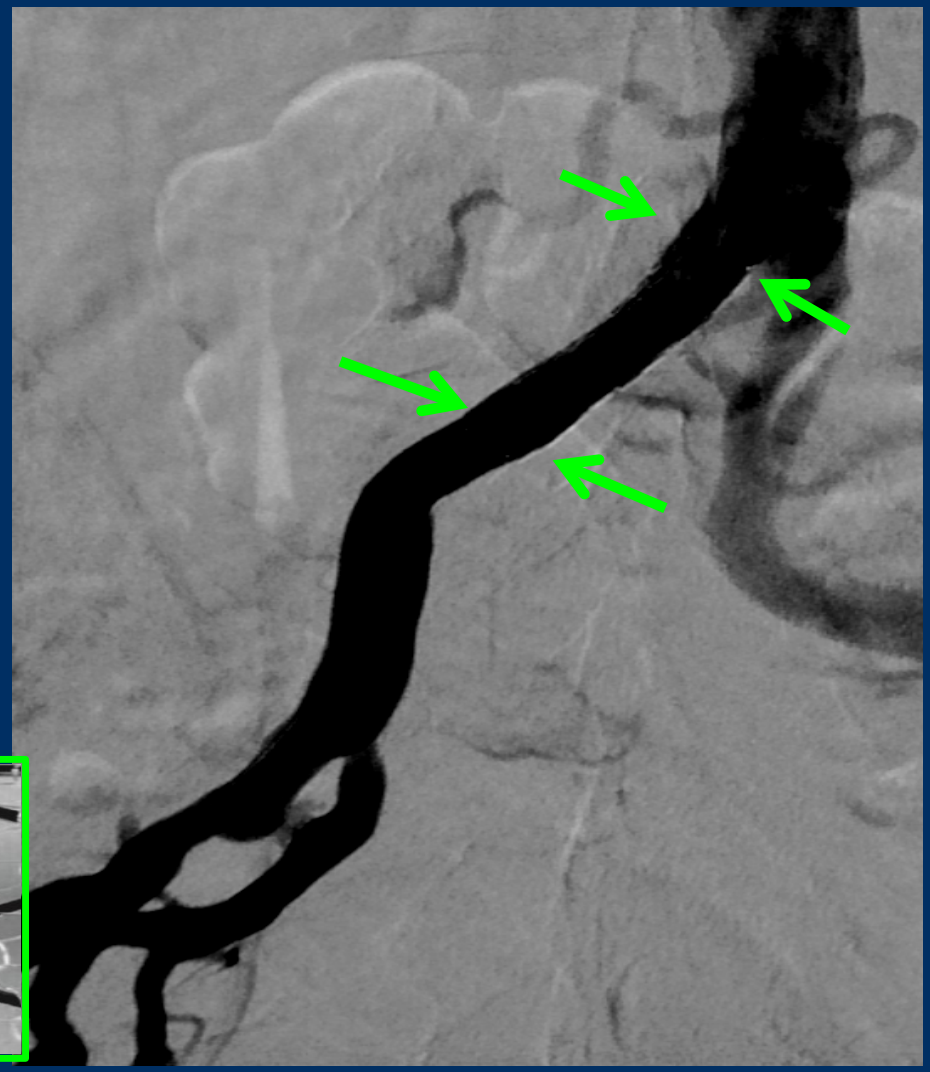
Optimal 6mo follow-up

Thrombus-containing/high-embolic risk lesions in iliacs







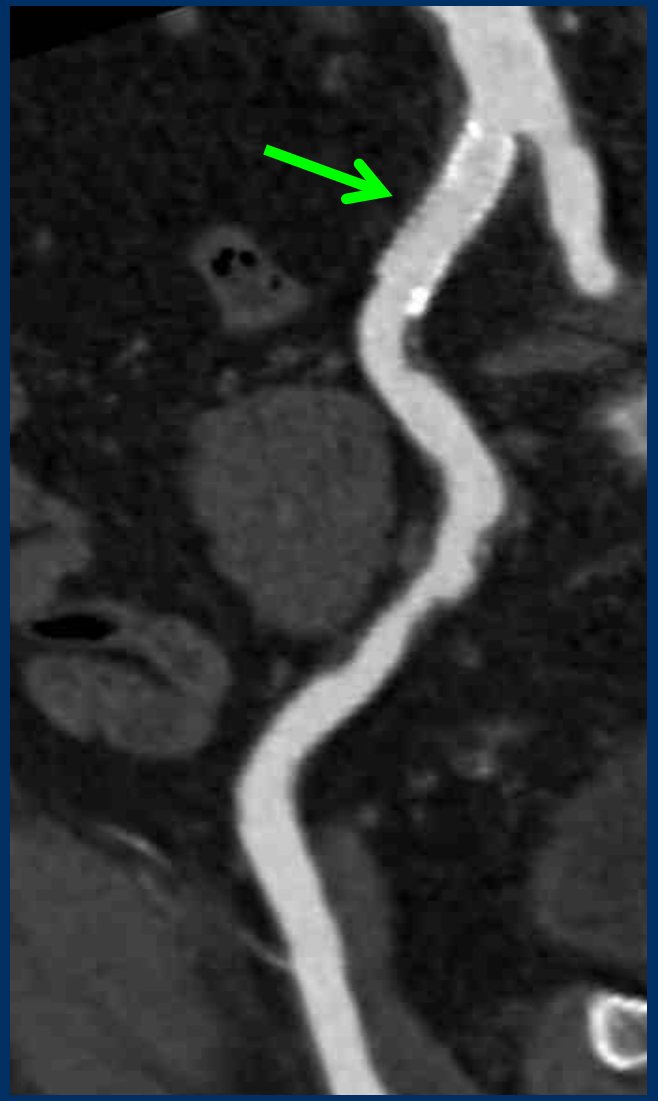


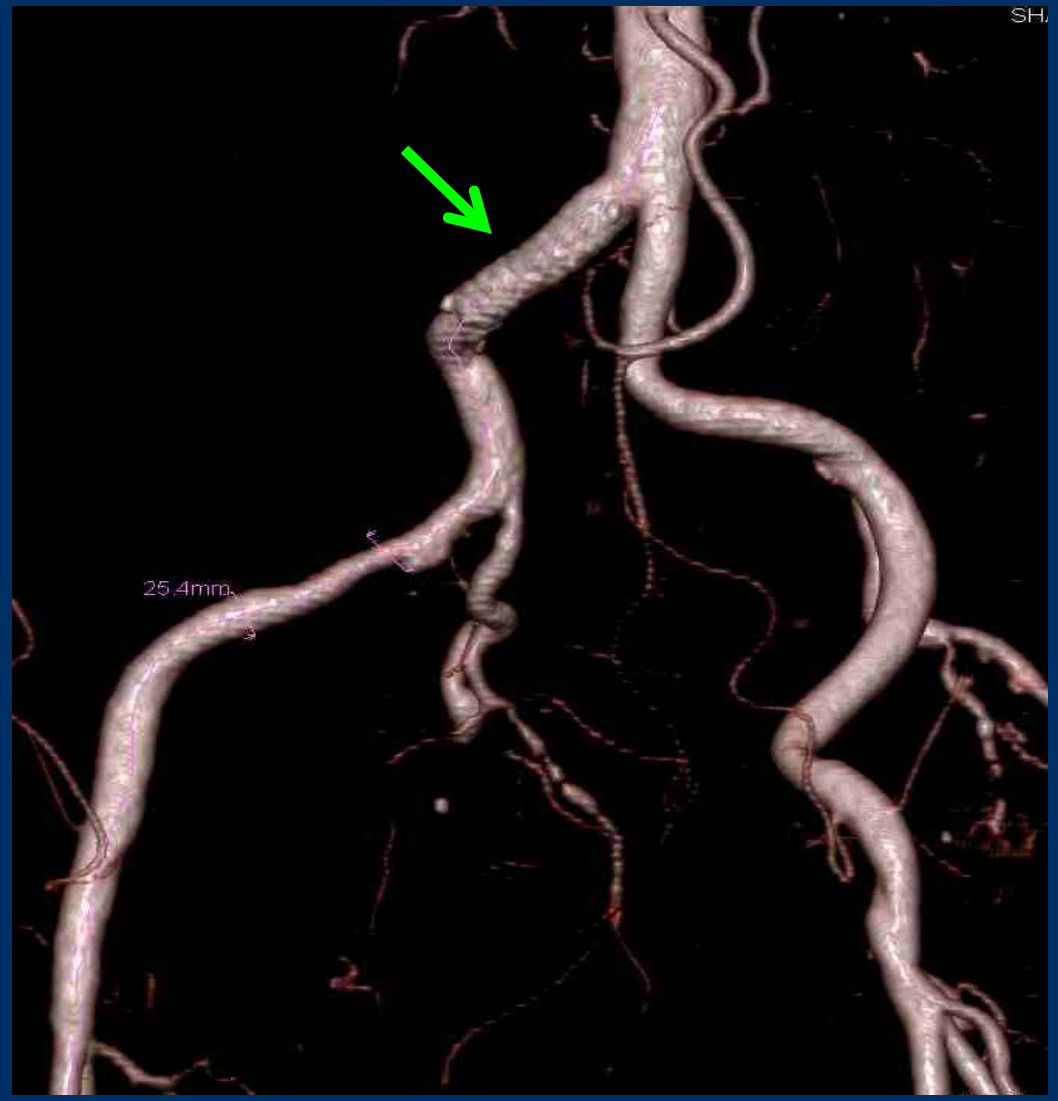
Acute procedural result

Thrombus-containing/high-embolic risk lesions in iliacs

MicroNet-covered stent

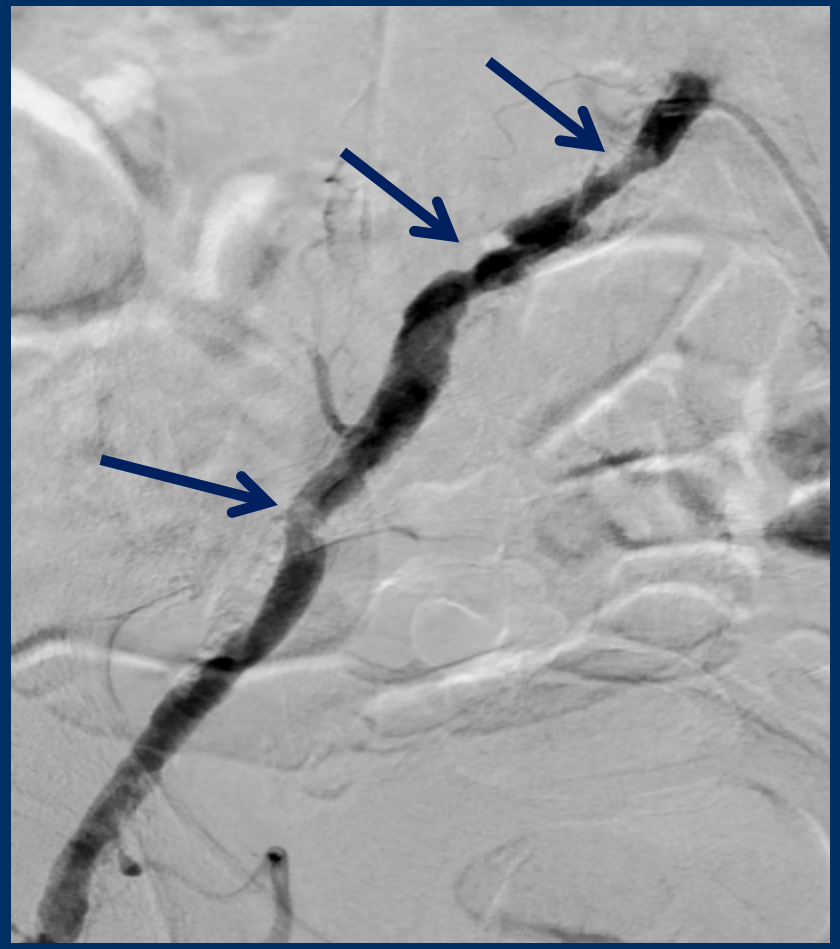
Optimal anatomic result @follow-up

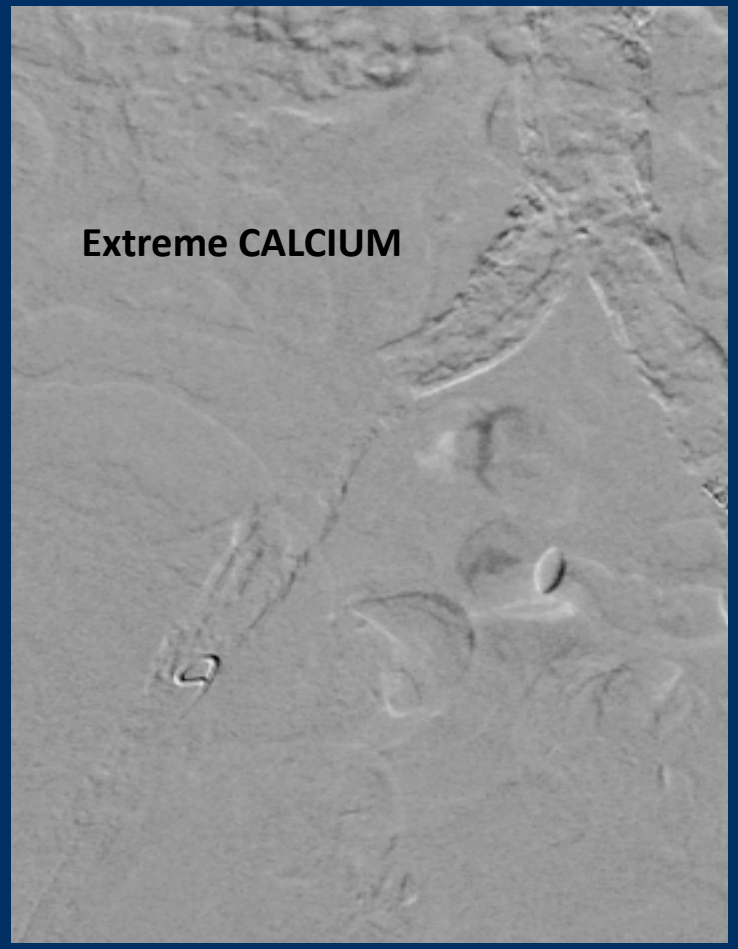


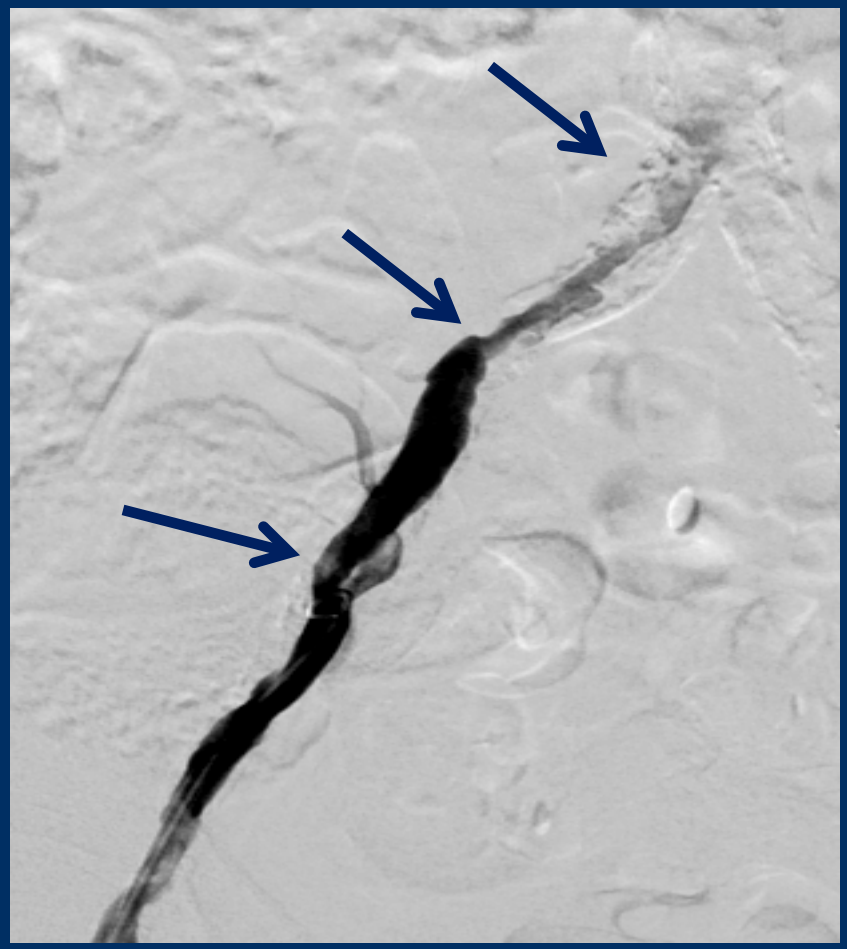


(V) Higly calcific disease

(note: adequate radial force need)







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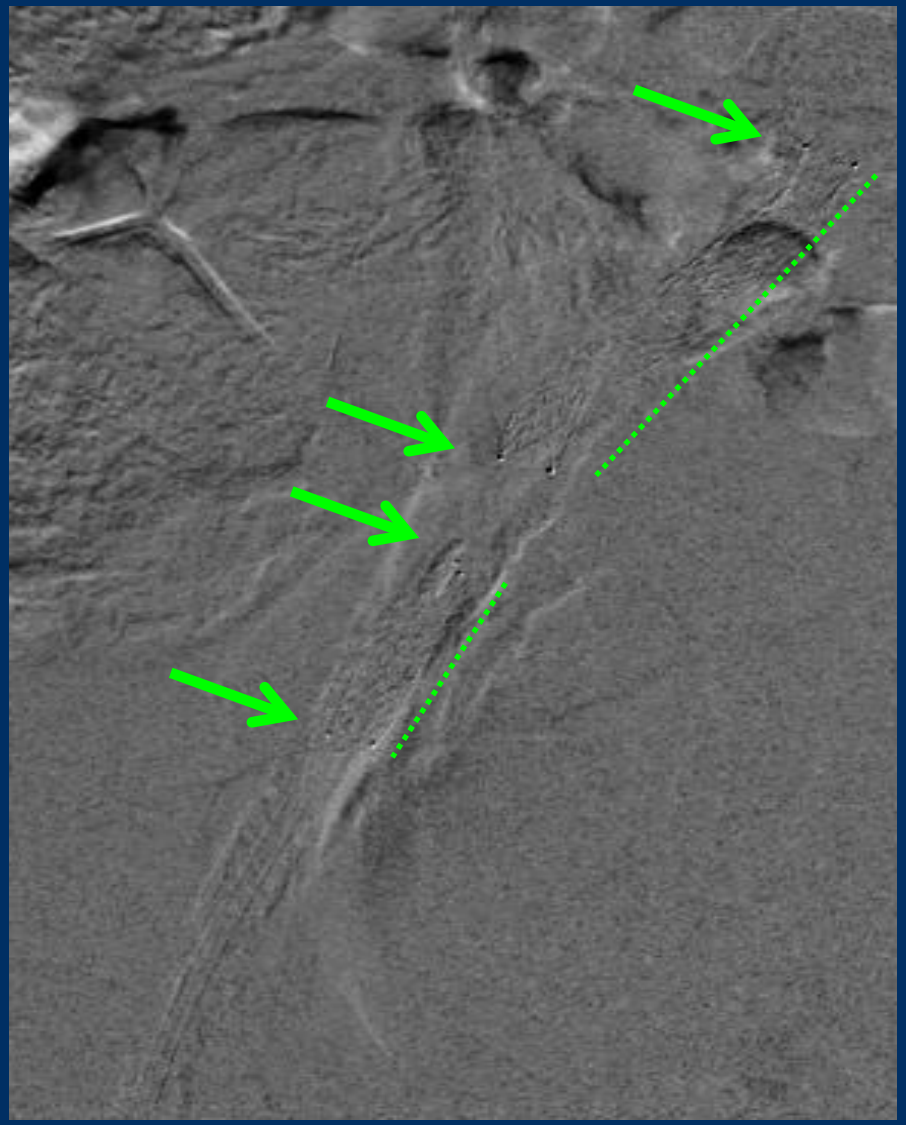
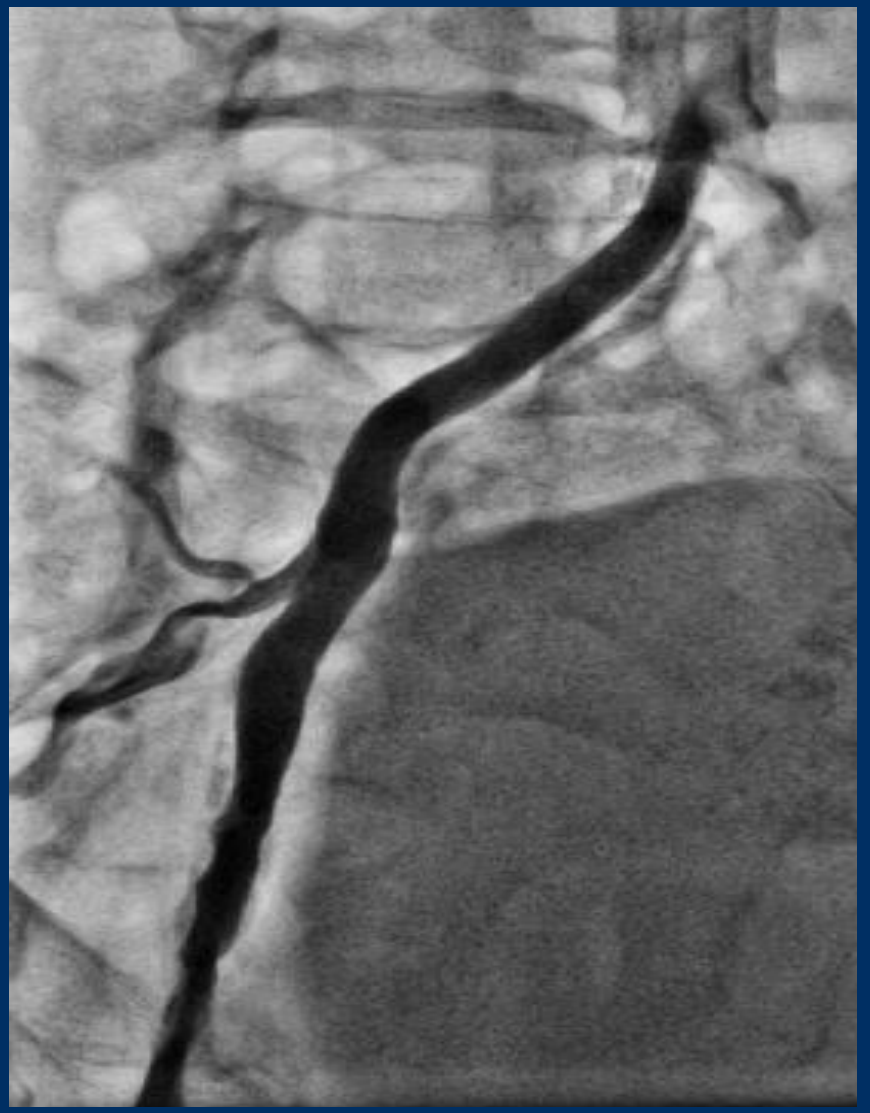
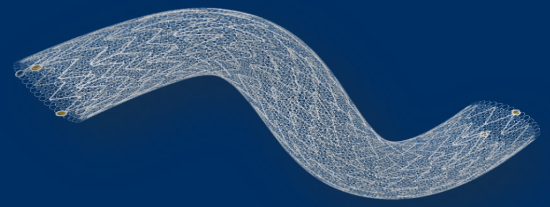
(note adequate radial force need)

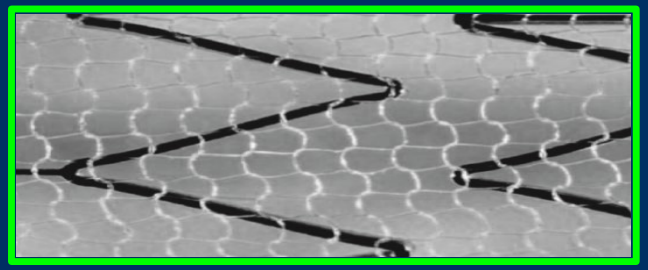




MicroNet-covered stent



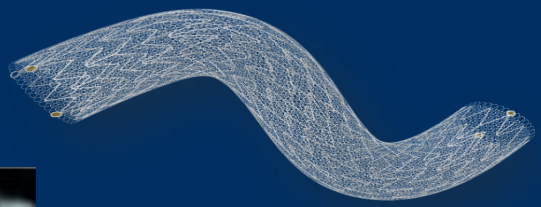
Acute Procedural Result

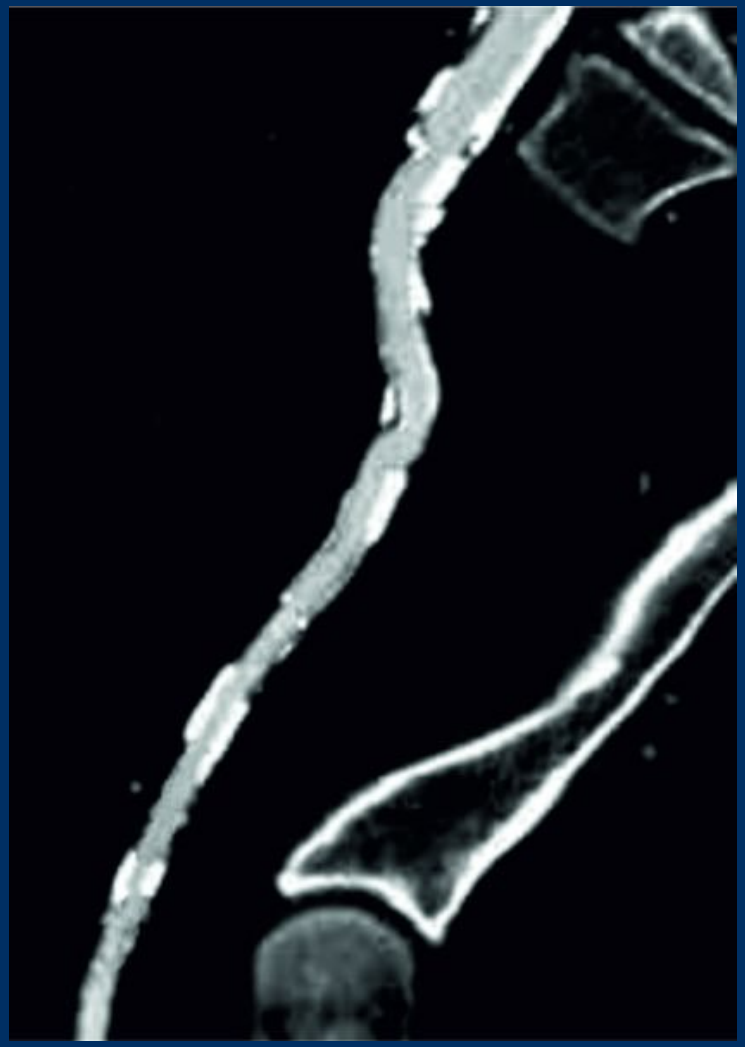


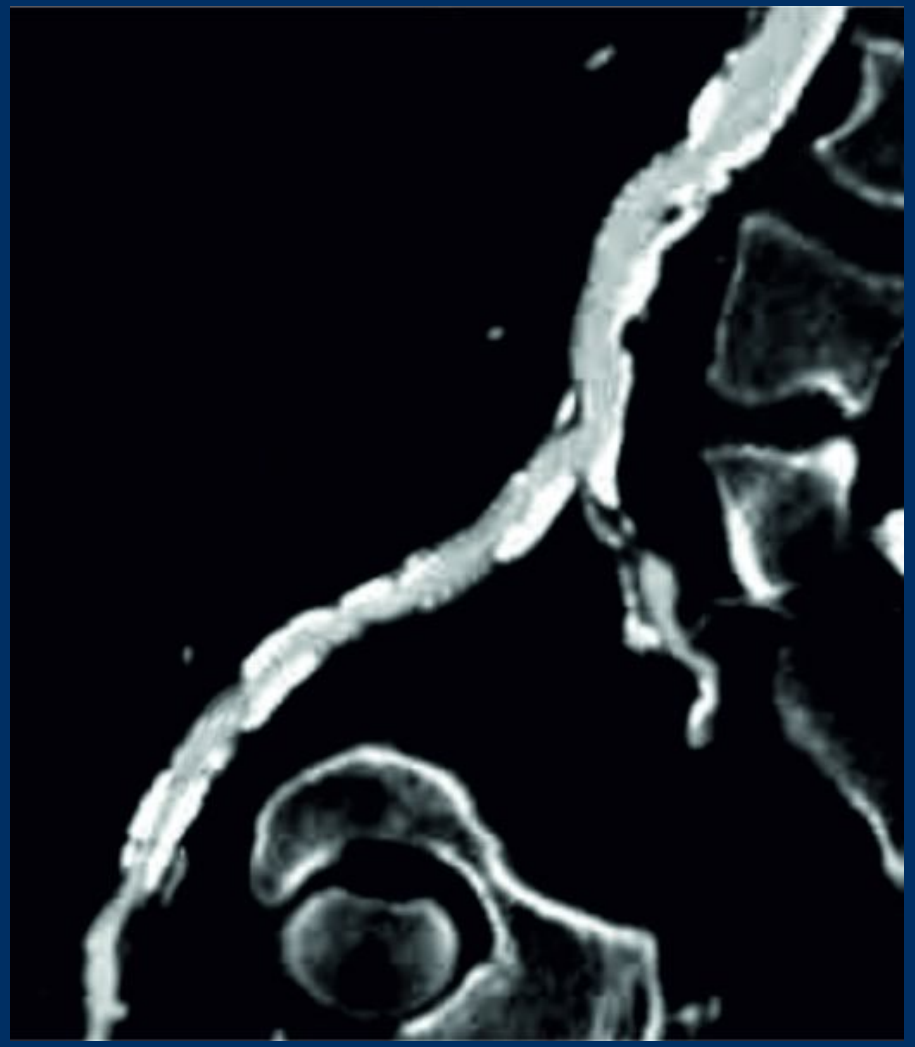
(V) Higly calcific disease

(note: adequate radial force provided)

MicroNet-covered stent







Optimal anatomic result @ 6mo

6 mo **OUTCOMES** (Primary endpoint = CTA)

65 patients (100%)

Imaging follow-up Performed (per patient)	
CTA	58 (89.2 %)
Catheter Angiography	3 (4.6 %)
Doppler-Duplex ultrasound (renal failure progr.)	4 (6.2 %)

Clinical (per patient)

Clinical improvement (claudication distance increase and/or limb saved) – 100%

Death/MI/Stroke – 1 (MI)

Amputation – 0

Restenosis rate (per lesion treated)

In-stent 0 (0.0%)

In-segment 1 (1.3%)

(progression of edge stenosis treated by adding another CGuard stent)

Conclusions

In increased-risk iliac artery lesions requiring revascularization, the MicroNET-covered stent:

- is safe and effective
- allows to optimize the angiographic result in absence of embolism or other complications
- achieved 100% primary patency in absence of ISR by 6 mo